

simply increasing penalties for criminals that choose to divert drugs into the United States or sell counterfeit drugs.

Current penalties for illegally diverting drugs in the United States change arbitrarily based on the location where the drugs are manufactured. Our bill addresses this disparity by enforcing the same penalties for diverting drugs made outside the United States as for those made inside the United States. To ensure public health and to enhance consumer confidence, it is critical that Congress eliminate these differing penalties for certain types of diversion and counterfeiting.

The second provision I wish to call attention to is a bipartisan proposal from Senators BENNET, BURR, and CASEY. These fine Senators have joined together to address how clinical trials are designed early on in their development. By offering guidance on how to include the intended patient population, especially those with rare diseases, drug sponsors can craft trials that generate useful data for health professionals and patients to review.

This bill builds upon the success of other expanded access provisions that put the patient at the heart of the healthcare system. FDA does consummate work when reviewing products for market, but including a wider patient mix, when appropriate, will enable phase I, II, and III trials to be more complex. I strongly believe that accurately portraying the intended patient population in a clinical trial is key to ensuring that drugs are both safe and effective.

I support this bill, but I also feel compelled to speak for a moment on the OPEN ACT. While not included in the package being debated today, the provisions of the Orphan Product Extension Now Accelerating Cures and Treatments Act—a bill I introduced this Congress with Senator MENENDEZ and last Congress with Senator KLOBUCHAR—would promote new therapies for rare diseases.

New therapies are essential to help the nearly 30 million Americans suffering from a rare disease or condition. Because complex rare diseases with small patient populations have limited market potential, there are few economic incentives to develop new drugs targeting those diseases. While there are 7,000 rare diseases that impact millions of Americans, 95 percent of these diseases have no treatment. All too often, misconceptions about the dangers of exclusivities keep bipartisan measures from being introduced. We must remain focused, however, and remember that, each day we delay in getting treatments to the rare disease community, patients and their families suffer.

Drug companies possess considerable scientific knowledge on drugs that have already been approved for common diseases. Some of these drugs could be repurposed for the treatment of rare diseases. Repurposing drugs is

faster, less expensive, and generally less risky than traditional drug development.

The OPEN ACT would encourage such repurposing by providing an additional 6 months of market exclusivity to drugs that are repurposed and approved by FDA for a rare disease or condition.

Finding legislative ways help medical innovators treat rare diseases has been among my top priorities for over 30 years, since I first championed the bipartisan, bicameral Orphan rug Act in 1983. The OPEN ACT is a natural next step in expanding that effort to close the gap for rare diseases for which we have yet to develop treatments. In addition to increasing the number of rare disease therapies, this legislation will boost innovation and provide safer options for rare disease patients using drugs off-label. My bill enjoys enormous support with the backing of over 225 rare disease organizations and patient advocacy groups, not to mention overwhelming support from academic medical and research centers.

Although this provision is not in the bill before us, I have had assurances from Chairman Alexander that he will continue working with me and the cosponsors of this bill to see it become law. I have spoken to Ranking Member MURRAY in the past about it, and I remain optimistic that my colleagues share my concern for the rare disease community and are willing to advance this legislation in the future. I would like to thank the chairman and ranking member for their dedication to children and families in need.

I wish to conclude by reminding my colleagues that many of the debates that have led to the bill before us today are the culmination of years of experience. When I led the effort to pass what became Hatch-Waxman, the true impact of that law dwarfed even our loftiest hopes. Hatch-Waxman was a resounding success because Senators and Congressmen worked together to improve our country's situation and reduce barriers to market entry. This bill is vital to continuing that goal, and I am pleased to see where the negotiations have landed.

#### TAX REFORM

Mr. HATCH. Mr. President, last week, I joined the Senate majority leader, the Speaker of the House, the chairman of the House Ways and Means Committee, the Treasury Secretary, and the Director of the National Economic Council in issuing a joint statement on tax reform.

I ask unanimous consent that the text of the joint statement be printed in the RECORD at the conclusion of my remarks.

Since the statement's release, critics and naysayers have said quite a bit, some even going so far as to declare their opposition to the statement. That is a little odd, given that the state-

ment is not a bill or a tax plan; it is simply a statement of agreed upon principles for tax reform.

That is not to say it was insignificant. Quite the opposite, in fact. The joint statement is an important development in the overall tax reform effort for several reasons.

For example, over the past several months, the favored tax reform narrative among some in the pundit class has been that Republicans are deeply divided. According to this narrative, Republicans in the Senate, the House, and the administration all have such fundamentally different views on tax reform that it will be impossible for us all to get on the same page.

Some of that was, to use an outdated description, pure poppycock.

When the administration puts out a framework that calls for a 15 percent corporate tax rate while the House blueprint has a 20 percent rate target, that is not really a disagreement. Both sides want to lower the corporate rate significantly, and the general idea in both cases is to reduce the rate as much as is reasonably possible.

Admittedly, there were some key differences of opinion. At the outset of this Congress, with a newly elected Republican President, it was fair to say that the House, Senate, and White House were on different pages when it came to some aspects of tax reform.

However, with last week's release of the joint statement, the leaders in this effort—in both congressional chambers and in the executive branch—have declared that, as of now, we are singing off the same song sheet. There are, of course, details that will need to be worked out, but all parties are in agreement on the key principles and have enough confidence that the process can move forward in Congress without the fear that the House, Senate, or administration will take drastically different approaches in crafting a tax reform package.

That is very significant. I have been working on tax reform for more than 6 years now, and this is the first time that we have had anything approaching this level of unity across the various Chambers and branches of government.

Another significant marker in the joint statement is the agreement that the tax-writing committees will do the lion's share of the work in producing the actual tax reform legislation and that the leaders are committed to moving through regular order, by which I mean committee markup processes prior to floor consideration.

This is key because one of the criticisms I have heard about Republicans' tax reform efforts is that the bill is being drafted behind closed doors I have even been scolded, sometimes pointedly, over why I have not held a Finance Committee hearing on "the bill," even though there is no complete bill in place at this time.

Outside groups, some overtly aligned with the Democrats, have already put forward budget scores for the House

blueprint and the President's tax framework, even though there are not enough specifics in place to score anything yet. Those scores, generated by whatever is in the imagination of the outside groups, and not based on any facts, tell tall tales. They say there will be tax cuts for the rich, big businesses and a parade of horrors. Democrats here in the Senate, as well, have spoken of the horrors of the Republican "tax plan," even though there is not a detailed plan in place. Again, the horrors represent pure fiction.

It is simply not the case that a bill is being drafted behind closed doors. It was never going to be the case. I have stated several times in recent months that I intended to have a robust and transparent process for tax reform in the Senate. The joint statement confirms that both chambers of Congress will take that kind of approach.

The Finance Committee is already hard at work. We have been talking about specific reform proposals for months now, and every member on the majority side of the committee is ready to do the work. More broadly, the committee has been at work in a bipartisan way on tax reform for many years now.

We have a number of great members on the Finance Committee, all of whom—at least on the Republican side—are committed to working toward this effort. I will continue to gather their input with an eye toward crafting a tax reform bill and moving it through the committee this fall. Once again, the committee process is going to be robust; I intend to hold multiple hearings and full markup.

The joint statement also noted that Republican leaders hoped that our Democratic colleagues would be willing to participate in this effort.

That should be no surprise. I have been calling on my Democrat friends to work with us on tax reform for months, even years.

For months now, I have been come to the floor on multiple occasions to ask my Democratic friends to come to the table.

I held a bipartisan hearing on tax reform in the Finance Committee just a few weeks ago, where we heard from experts on both sides of the aisle.

Earlier this week, the committee had another bipartisan hearing, this one on affordable housing. Of course, most of the Federal affordable housing incentives are found in the Tax Code, meaning that issue will undoubtedly be part of the larger discussion.

These hearings are just the latest in very long line of bipartisan, tax-related hearings in the Finance Committee.

So there really shouldn't be any doubt that, when I sign onto a statement that includes a call for bipartisanship, the call is both serious and sincere.

In addition, there is quite a bit of bipartisan agreement over the policy principles noted in joint statement.

As I said here on the floor just a few weeks ago, a number of Democrats—in-

cluding a number of our Senate colleagues and the two most recent Democratic Presidents—have expressed support for lowering the U.S. corporate tax rate, which is the highest in the industrialized world.

Prominent Democrats, including the distinguished minority leader, have publicly supported reforms to our international tax system in order to make American businesses more competitive and prevent erosion of our tax base.

Both of these concepts are prominently mentioned in our joint statement.

The statement also talks about tax relief for middle-class families and reduced burdens on small businesses. Democrats, last time I checked, were largely in favor of this as well.

So long story short, there is nothing in the statement, either in terms of process or policy, that should discourage a number of Democrats from getting on board with this effort.

Yet, earlier this week, every member of the Senate Democratic Caucus—except three—signed onto a letter they purported to be a call for compromise and bipartisanship. However, if you read the details of the letter, it was really a set of up-front demands peppered in between political attacks.

First and foremost, my colleagues demanded in their letter that Republicans not use budget reconciliation to move a tax reform bill.

That has been a precondition for Democratic involvement in this effort for months now, among other demands unrelated to tax reform, and, as I have said many times, it is preposterous. The demand that Republicans agree up-front to a particular process is really unprecedented and, not to put too fine a point on it, a little nonsensical.

If Democrats are willing to engage in good faith on tax reform, why would they first demand that we ensure their ability to block it from ever even coming to the floor before they would be willing to engage on the substance? The logic is a little dizzying, to say the least.

On top of that, if reconciliation remains on the table, why would that stop Democrats from agreeing on the substance?

Obviously, budget reconciliation gives the majority the tools it needs to move legislation—under specified rules and conditions—without the threat of a filibuster, but nothing in the rules requires reconciliation to be partisan. In fact, historically speaking, tax bills moved through reconciliation tend to get bipartisan support. For example, the so-called Bush Tax Cuts of 2001 and 2003 were passed through reconciliation; yet there were both Republicans and Democrats voting in favor of the package.

Recent history shows that working together on the substance of policy is not precluded by the existence of a reconciliation instruction.

In 2009, with a reconciliation instruction in place, Senate Republicans in

the Finance Committee participated in the healthcare reform process, with hearings, roundtables, and bipartisan discussion groups, before we were shut out of the final ObamaCare bill. Republicans did not operate as though there was a prerequisite of no reconciliation before discussion could occur.

In 2013, with a \$1 trillion tax-hike reconciliation instruction in place, Senate Republicans in the Finance Committee participated in discussions that produced 10 bipartisan tax option papers; we participated in what was called a blank slate approach to tax reform; and we participated in discussion draft conversations. Republicans did not operate as though there was a prerequisite of no reconciliation before discussion could occur.

Now, our friends on the other side are critical of us when we follow the path they, themselves, took. They are insisting that we do what they would not do when similarly situated. They are not participating on the same constructive basis we did when we were in their place. From their leader on down, they act as if the past does not exist or that we are ignorant of it. Before applying too clever a rhetorical lash to those on this side, my friends on the other side should heed the advice of Lord Byron: "Keep thy smooth words and juggling homilies for those who know thee not."

If Democrats will work with us to reach agreement on the substance of tax reform, the process by which it moves through the Senate shouldn't really be a concern. Any implication that the process will necessarily dictate the substance is misleading.

Ideally, the tax reform process would be bipartisan, particularly here in the Senate. That would be the best-case scenario for the effort.

In a perfect world, reconciliation would not be necessary.

For that to happen, the Democrats would have to be willing to engage in a reasonable manner. In my view, opening the discussion with a demand that Republicans unilaterally disarm and commit to not using the tools we have under the rules of the Senate—the very tools that have been used by both sides in the past—smacks of disingenuousness. If they are truly willing to engage constructively on these efforts—and I hope they are—we should begin by talking about the substance, not dealing with process demands.

I hope that what we are seeing is posturing. I hope that my Democratic colleagues will recognize the significance of the unity expressed in last week's joint statement and get on board for what will hopefully be a historic effort.

If they do not, Republicans should be willing to use the tools at our disposal to move tax reform without Democratic support. That would include reconciliation.

The majority leader has indicated that he is willing to go that way. I am willing to go that way as well.

However, to get us to the point, a number of things have to happen, not

the least of which is the passage of budget resolution. For now, I am focusing on the substantive policies and proposals, and I will keep working with my colleagues on the Finance Committee to deliver on the tasks we were charged in the joint statement.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[July 27, 2017]

#### JOINT STATEMENT ON TAX REFORM

WASHINGTON.—Today, House Speaker Paul Ryan (R-WI), Senate Majority Leader Mitch McConnell (R-KY), Treasury Secretary Steven Mnuchin, National Economic Council Director Gary Cohn, Senate Finance Committee Chairman Orrin Hatch (R-UT), and House Ways and Means Committee Chairman Kevin Brady (R-TX) issued the following joint statement on tax reform:

“For the first time in many years, the American people have elected a President and Congress that are fully committed to ensuring that ordinary Americans keep more of their hard-earned money and that our tax policies encourage employers to invest, hire, and grow. And under the leadership of President Trump, the White House and Treasury have met with over 200 members of the House and Senate and hundreds of grassroots and business groups to talk and listen to ideas about tax reform.

“We are all united in the belief that the single most important action we can take to grow our economy and help the middle class get ahead is to fix our broken tax code for families, small business, and American job creators competing at home and around the globe. Our shared commitment to fixing America’s broken tax code represents a once-in-a-generation opportunity, and so for three months we have been meeting regularly to develop a shared template for tax reform.

“Over many years, the members of the House Ways and Means Committee and the Senate Finance Committee have examined various options for tax reform. During our meetings, the Chairmen of those committees have brought to the table the views and priorities of their committee members. Building on this work, as well as on the efforts of the Administration and input from other stakeholders, we are confident that a shared vision for tax reform exists, and are prepared for the two committees to take the lead and begin producing legislation for the President to sign.

“Above all, the mission of the committees is to protect American jobs and make taxes simpler, fairer, and lower for hard-working American families. We have always been in agreement that tax relief for American families should be at the heart of our plan. We also believe there should be a lower tax rate for small businesses so they can compete with larger ones, and lower rates for all American businesses so they can compete with foreign ones. The goal is a plan that reduces tax rates as much as possible, allows unprecedented capital expensing, places a priority on permanence, and creates a system that encourages American companies to bring back jobs and profits trapped overseas. And we are now confident that, without transitioning to a new domestic consumption-based tax system, there is a viable approach for ensuring a level playing field between American and foreign companies and workers, while protecting American jobs and the U.S. tax base. While we have debated the pro-growth benefits of border adjustability, we appreciate that there are many unknowns associated with it and have decided to set this policy aside in order to advance tax reform.

“Given our shared sense of purpose, the time has arrived for the two tax-writing committees to develop and draft legislation that will result in the first comprehensive tax reform in a generation. It will be the responsibility of the members of those committees to produce legislation that achieves the goals shared broadly within Congress, the Administration, and by citizens who have been burdened for too long by an outdated tax system. Our expectation is for this legislation to move through the committees this fall, under regular order, followed by consideration on the House and Senate floors. As the committees work toward this end, our hope is that our friends on the other side of the aisle will participate in this effort. The President fully supports these principles and is committed to this approach. American families are counting on us to deliver historic tax reform. And we will.”

#### FDA REAUTHORIZATION BILL

Mr. REED. Mr. President, today, the Senate passed the Food and Drug Administration Reauthorization Act of 2017, FDARA, to reauthorize user fees and other programs at the FDA to ensure that new, safe, and effective treatments get to patients in need as quickly as possible to save lives and greatly increase quality of life. While I have long preferred that Congress appropriate funding to the FDA for this purpose to avoid any conflicts of interest, I have supported user fee bills and will do so again today, as it represents a bipartisan pathway for timely drug approvals. I am pleased that this legislation increases the amount of funding that drug and device companies will contribute to the approval process. However, I am disappointed that this legislation does not address drug pricing in a comprehensive way, as I have long advocated. I will continue to work with my colleagues to press for Senate action on this critical issue.

FDARA includes a number of key provisions I worked on to improve the pipeline for new pediatric drugs and devices. In particular, this legislation will reauthorize funding for critical pediatric programs such as pediatric clinical trials at the National Institutes of Health and the Pediatric Device Consortia grants under the FDA. In addition, this legislation will spur more pediatric drug development because of critical reforms to require drug companies to begin consideration of pediatric studies earlier in the drug development process. FDARA also takes important steps to spur drug development for and better consideration of the needs of neonates, recognizing that treatments for infants must be considered differently than for teenagers.

Having worked for many years to improve access to care for children with cancer and childhood cancer survivors, I am also pleased to support the bill’s new requirements for more pediatric studies on treatments for cancer. These provisions are designed to spur new and better treatments for children suffering from cancer. However, I believe that we should be making these changes to support new treatments for

all diseases impacting children, not just those with cancer. While we were unable to go that far in this bill, we were able to add a study of this issue. I look forward to seeing the results and working with my colleagues to expand these requirements in subsequent legislation. I am also concerned that this legislation does nothing to limit the ability of drug companies to benefit from exemptions from current pediatric study requirements. I filed an amendment to FDARA to close the most egregious of these loopholes in which a drug company can technically be exempted from pediatric study requirements because the treatment would only be used for a rare pediatric condition. I would hope that my colleagues on both sides of the aisle could agree that this loophole must be closed.

FDARA is an important step forward and an example of strong bipartisan health legislation in this Congress. I hope that we can continue this work, and not return to the partisan efforts to repeal the Affordable Care Act that occupied this body for much of the year.

Mr. MENENDEZ. Mr. President, I am pleased the Senate advanced H.R. 2430, the FDA Reauthorization Act. This bipartisan, bicameral legislation ensures Americans will continue to have access to safe medications and the FDA has the tools they need to continue our Nation’s approval process remains the gold standard. I am also pleased to see tropical disease priority review voucher state that a sponsor qualifies for a neglected tropical disease priority review voucher under existing law until September 30, 2017, so long as they submit at least one portion of a human drug application by that date.

I would like to ask Senator ISAKSON if it is our intention to allow for sponsors who have been working in good faith with the Food and Drug Administration on a human drug application for a product that addresses a neglected tropical disease to qualify for a priority review voucher, as long as they begin a rolling submission to the agency by September 30, 2017?

Mr. ISAKSON. Mr. President, as my colleague Senator MENENDEZ indicated, the intent of the language in the FDA Reauthorization Act is this: so long as the submission process for a given product is begun by the sponsor on or before September 30, 2017, the product would qualify for a priority review voucher under the neglected tropical disease priority review voucher program.

Mr. MENENDEZ. Mr. President, I thank my colleague, Senator ISAKSON, for clarifying the language. It is important to provide this clarity to ensure products, for which at least one portion of the application is submitted in accordance with Section 506(d) of the Food, Drug & Cosmetic Act by September 30, 2017, qualify for the vouchers under current law.